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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,125	04/02/2004	Nabil L. Muhanna	M112 1140.1	1507

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EXAMINER

SWIGER III, JAMES L

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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12/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/817,125

Applicant(s)

MUHANNA ET AL.

Examiner

James L. Swiger

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 30-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/2/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1, 4-6, 8, 18, 23, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar (U.S. Patent No. 5,910,142).

Tatar discloses a device having a pedicle screw (100), and a pair of spaced-apart threaded posts (125a and 125b), that may be defined as a yoke since it harness or the components of the device. The threaded posts define a channel (122), a ball collet (Fig. 3) that is insertable into the channel, a rod (150) having first and second ends, wherein the first end is capable of being inserted into the ball collet bore (See fig. 5), a threaded cap (140) configured and dimensioned to mate with the threaded posts and that which provides a compressive force on the ball collet (see lines 14-15 of the abstract). The device disclosed by Tatar is also capable of being adjusted in a disassembled state, but in the assembled state (see Fig. 5) the ball collet (130) is seated in the channel (126), which may be considered concave. The rod also goes through the bore of the collet and the cap (140) is screw-coupled to the posts (125a and 125b), which have threads on the inner surfaces (124). These threads are considered integral at least with the insertion portion of the yoke portion. The yoke portion is considered fixed relative to the threaded

insertion portion (upper part), which may be considered a functional limitation of the structure. Considering the entire upper portion as a yoke, the individual 'posts' of the yoke are threaded on the inner surfaces and create a concave seat.

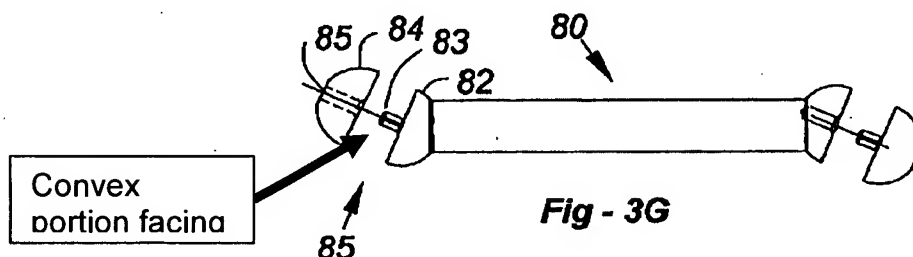
With regard to the threaded posts being fixed relative to the threaded portion, it is noted that the Tatar device comprises several parts, i.e. the yoke and insertion portion, which are rigidly secured together as a single unit when they are assembled. However, it would have been an obvious matter of design choice that the constituent parts are so combined as to constitute a unitary whole or structure, at least being fixed in a disassembled state. In re Larson, 144 USPQ 347 (CCPA 1965).

Claim 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar '142. in view of Doubler et al. (U.S. PG-PUB 2005/0070899 A1). Tatar discloses the claimed invention except for a crown having a cylindrical skirt and a radially inwardly projecting flange. Doubler et al. '899 discloses a crown with a cylindrical skirt and flange (see Figure X below) that enables the user to engage the outer spherical surface of the pedicle screw (par 0066) while this skirt rests on the inwardly projecting flange to more evenly distribute force throughout the connection (see bottom of par. 0075). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar having at least the crown and skirt and inwardly projecting flange in view of Doubler et al. to better enable the surgeon to better secure the rods in the place after adjusting during the surgical procedure.

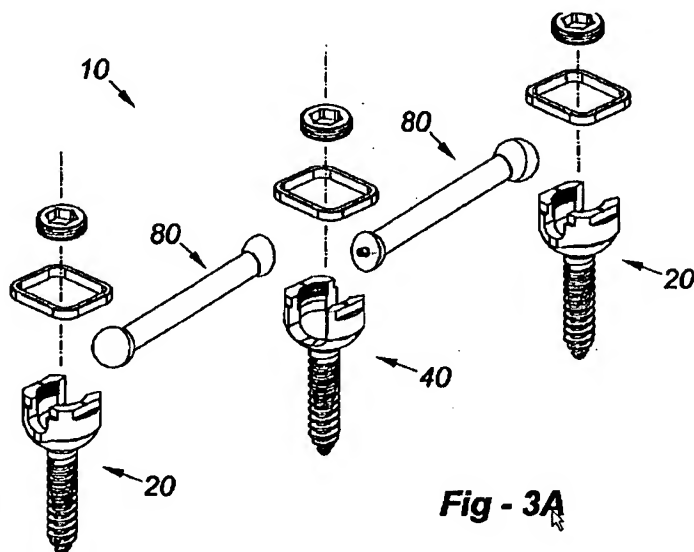
Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar '142 in view of Sgier et al. (US Publication 2005/0171538). Tatar discloses the claimed invention except for a plurality of slots spaced about the surface of the ball collet in alternating fashion to connect with the bore. Sgier et al. disclose slots (6) that communicate with the surrounding area of the bore (par. 0019) to better fit within the cavity (par. 0012). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar having at least a ball collet with alternating slots in view of Sgier et al. to better secure the rod and collet within the bore.

Claims 10-18, 17-22, and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar '142 in view of Ferree (US Patent 6,802,844). Tatar discloses the claimed invention except for at least a second end of the rod to have a spherical ball member, a rod having a second end with a convex surface that faces an inboard side (having a central recess) of a second end, multiple components (i.e. first, second, or third pedicle screws, first and second caps, multiple pedicle screws and rods with ends).

Ferree disclose a spinal apparatus having a rod with at least one bulbous end (Fig. 36), and an end with a convex end facing the inboard side of an end (see below)



Ferree also discloses multiple components (i.e. first, second, or third pedicle screws, first and second caps, multiple pedicle screws and rods with ends); see below.



These modifications help the device to better conform to the to the vertebrae and allow for various angles (see Col. 8, lines 36-39) of the components to better fit to the spine. See also Col. 2, lines 14-38). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar having at least at least a second end of the rod to have a spherical ball member, a rod having a second end with a convex surface that faces an inboard side (having a central recess) of a second end, and multiple components to better arrange the assembly in use.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar in view of Griss (US Patent 5,536,268). Tatar discloses the claimed invention except for the pedicle screw to be formed from titanium or an alloy thereof. Griss discloses within the scope of the invention the use of titanium or similar allow (Col. 6, lines 53-60). It would have been obvious to one having ordinary skill in the art at the time the invention

was made to construct the device of Tatar having at least the use of titanium as a material in view of Griss so the invention is biocompatible.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Tatar '142 and Sgier et al. '538 and Griss '268.

Tatar discloses a device having a pedicle screw (100), and a pair of spaced-apart threaded posts (125a and 125b), that may be defined as a yoke since it harness or the components of the device. The threaded posts define a channel (122), a ball collet (Fig. 3) that is insertable into the channel, a rod (150) having first and second ends, wherein the first end is capable of being inserted into the ball collet bore (See fig. 5), a threaded cap (140) configured and dimensioned to mate with the threaded posts and that which provides a compressive force on the ball collet (see lines 14-15 of the abstract). The device disclosed by Tatar is also capable of being adjusted in a disassembled state, but in the assembled state (see Fig. 5) the ball collet (130) is seated in the channel (126), which may be considered concave. The rod also goes through the bore of the collet and the cap (140) is screw-coupled to the posts (125a and 125b), which have threads on the inner surfaces (124). These threads are considered integral at least with the insertion portion of the yoke portion. The yoke portion is considered fixed relative to the threaded insertion portion (upper part), which may be considered a functional limitation of the structure. Considering the entire upper portion as a yoke, the individual 'posts' of the yoke are threaded on the inner surfaces and create a concave seat.

Tatar disclose the claimed invention except for a ball collet with a plurality of slots in alternating fashion. Tatar discloses the claimed invention except for a plurality of

slots spaced about the surface of the ball collet in alternating fashion to connect with the bore. Sgier et al. disclose slots (6) that communicate with the surrounding area of the bore (par. 0019) to better fit within the cavity (par. 0012).

Tatar discloses the claimed invention except for the pedicle screw to be formed from titanium or an alloy thereof. Griss discloses within the scope of the invention the use of titanium or similar allow (Col. 6, lines 53-60).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Tatar having at least a ball collet with alternating slots or a material of titanium in view of the combination of Sgier et al. and Griss to better use the device and be associated with the body.

Response to Arguments

Applicant's arguments filed 4/24/2007 have been fully considered but they are not persuasive. In response the interview summary on 5/1/2007 and as amended in the claims, it is noted that the rejection has been overcome with regards to 35. USC 102, however still reads on the prior art of record. As noted above, Tatar teaches the invention as disclosed, despite the threaded insertion and the threaded posts being able to move in a disassembled state. However, it would have been an obvious matter of design choice to make the device unitary or one-piece to arguably have better fixation when placing the screw. Additionally one-piece designs are well known in the art (see also cited art of Griss '268, for example, Fig 8).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:
10/817,125
Art Unit: 3733

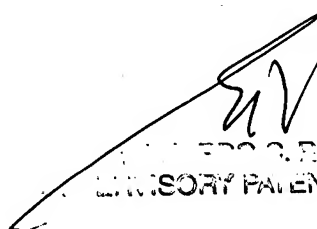
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11/30/07

JLS



EDG R. ROBERT
ASSISTANT PATENT EXAMINER